

## REMARKS/ARGUMENTS

Claims 1-6 are pending herein. Claims 1-4 have been amended hereby to correct minor matters of form and for clarification purposes, and claim 4 has been rewritten to depend from claim 1. New claims 5 and 6 added hereby depend from claim 1. Applicant respectfully submits that support for new claims 5 and 6 can be found in paragraphs [0111] and [0125] of the substitute specification, for example. Applicant respectfully submits that no new matter has been added.

1. The §112, second paragraph rejection of claims 1, 3 and 4 is noted, but deemed moot in view of the rewritten claims submitted above. Applicant respectfully submits that support for rewritten claims 1, 3 and 4 can be found in paragraphs [0030]-[0039] of the substitute specification, for example.

For at least the foregoing reasons, Applicant respectfully requests that the above rejection be reconsidered and withdrawn.

2. Claim 1 was rejected under §102(b) over Colarow. Applicant respectfully traverses this rejection. To the extent that this rejection might instead be applied against new claims 5-8, it is also respectfully traversed.

Independent claim 1 recites a semi-solid enteral nutrition product for enteral administration directly to a stomach or intestines of a patient from an external container connected to an external portion of a feeding tube provided through a through-hole of a stoma formed through a portion of the abdominal and stomach walls of the patient upon the application of pressure to the external container. The semi-solid enteral nutrition product comprises a semi-solid material having a substantially self-supporting consistency that deforms to flow under an externally applied load without liquefying and that is capable of containing a higher concentration of a nutrient component than a liquid. The semi-solid material comprises a liquid nutrient solution and a semi-solidifying agent comprising one of agar and a whole egg that is added to the liquid nutrient solution. The self-supporting consistency of the semi-solid enteral nutrition product remains substantially unchanged before, during, and after

enteral administration of the semi-solid enteral nutrition product into the patient, and is further maintained within the stomach or the intestines of the patient such that the semi-solid enteral nutrition product does not decrease liquefy due to the body temperature of the patient.

The semi-solidifying agent according to the present invention serves to increase the consistency of the nutrient liquid (i.e., thicken) such that the resulting semi-solid mixture has a substantially self-supporting consistency that is like a solid in that the mixture is stiff enough to define a shape that this not spontaneously reduced under atmospheric conditions. That is, a shape assumed by the semi-solid mixture will be maintained after that mixture has been removed from the mixing container, unlike a liquid, which will not maintain any specific shape after being removed from its container and instead flows to assume the shape of the new container or to spread outwardly if not otherwise confined. In other words, the consistency of the semi-solid mixture enables the semi-solid mixture to have a shaped form that is self-supporting and will not significantly deform without the application of an externally applied force thereto. The consistency of the semi-solid mixture is also like a liquid, however, in that the mixture will deform, for example, to flow from a container into a feed tube, under an applied pressure load. While the “shape” of the mixture may change under pressure with respect to the actual shape of the containers and the feed tube, the substantially self-supporting consistency of the semi-solid mixture does not substantially change while the enteral nutrition product is administered via the feeding tube, or even after the enteral nutrition product is administered into the body of the patient.

Further, the semi-solid consistency of the mixture constituting the enteral nutrition product is maintained even when the semi-solid enteral nutrition product is subjected to the temperatures of the enteral environment (i.e., the stomach and intestines of the body) that would otherwise lead to liquefaction due to body heat. Because the semi-solid enteral nutrition product according to the present invention maintains this self-supporting, yet deformable, semi-solid form, even within the patient, the enteral nutrition product will not flow, or back flow, like a liquid within

the stomach and/or intestines of the patient. In that manner, the chances of a patient experiencing regurgitation or reflux are reduced, which is beneficial to patients and caregivers alike, particularly for patients who cannot sit up and are restricted to a supine position, for example.

Applicant respectfully submits, however, that contrary to the PTO's assertion, Colarow's heat-stabilizing agent does not correspond to a semi-solidifying agent, and that Colarow does not even disclose the claimed semi-solidifying agent at all. That is, Applicant respectfully submits that Colarow's heat-stabilizing composition serves to prevent coagulation and separation of egg yolk and other proteins at elevated temperatures in emulsions when the emulsions are heated during homogenization (e.g., sterilization) processes. Moreover, Applicant respectfully submits that Colarow clearly teaches the heat-stabilizing composition itself is not the egg yolk that it prevents from solidifying.

On the other hand, the semi-solidifying agent of the present invention itself is a whole egg, at least in one case, and is added to promote a physical change from a liquid state toward a solid state to achieve a semi-solid state with a substantially self-supporting consistency, not to prevent such a change like Colarow's heat-stabilizing composition. Indeed, Applicant respectfully submits that Colarow's heat-stabilizing composition actually promotes and achieves the opposite effect on the "nutrient" mixtures to which it is added compared to the claimed semi-solidifying agent.

Further, Applicant respectfully submits that Colarow does not include any disclosure whatsoever that the consistency of the heat-stabilized emulsions are, or even could be, substantially self-supporting and substantially constant before, during and after being delivered via a feeding tube into the enteral environment of a patient, as claimed.

In view of the above, Applicant respectfully submits that Colarow simply does not disclose any semi-solidifying agent, much less a semi-solidifying agent comprising whole egg, as recited in claims 1 and 6. Further, Applicant respectfully submits that Colarow does not disclose that such an otherwise undisclosed semi-solidifying agent comprises agar, as recited in claims 1 and 5.

For at least the foregoing reasons, Applicant respectfully submits that all claims pending herein define patentable subject matter over Colarow. Accordingly, Applicant respectfully requests that the above rejection be reconsidered and withdrawn.

3. Claims 1 and 3 were rejected under §102(b) over Ying's Rice Pudding with Chestnuts recipe (published in *The New Good Housekeeping Cookbook*). Applicant respectfully traverses this rejection.

Independent claim 1 is discussed above in section 2. Claim 3 recites a method for forming the semi-solid enteral nutrition product of claim 1, including the steps of providing a holder comprising one of the container and another vessel that is separate from the container, filling the holder with a liquid mixture of a liquid nutrient solution and the semi-solidifying agent, and performing a heat-treating step to heat treat the mixture and the holder containing the mixture. The heat-treating step comprises cooling the mixture when the semi-solidifying agent is agar, and the heat-treating step comprises heating the mixture when the semi-solidifying agent is a whole egg.

The PTO asserted that Ying's rice pudding recipe anticipates claims 1 and 3 simply because Ying's pudding recipe calls for three whole eggs. Applicant respectfully submits, however, that Ying's rice pudding recipe is just that, a recipe for making a dessert that is only intended for ordinary oral consumption (i.e., eating). Independent claim 1, on the other hand, specifically recites that the claimed enteral nutrition product is just that, an enteral product for direct delivery to the stomach or intestines of a patient via a feeding tube. Applicant respectfully submits that there is simply no disclosure whatsoever in Ying that once made, the rice pudding should, or even could, be used as an enteral nutrition product for direct administration to the stomach or intestines of a patient via feeding tube in the claimed manner, especially since the present application defines an enteral nutrition product specifically as being "not a food which is taken orally" (substitute specification, paragraph [0036]).

Further, Applicant respectfully submits that Ying does not include any disclosure whatsoever that the consistency of the rice pudding with chestnuts is, or

even could be, substantially self-supporting and substantially constant before, during and after being delivered via a feeding tube into the enteral environment of a patient (rather than eaten normally).

For at least the foregoing reasons, Applicant respectfully submits that all claims pending herein define patentable subject matter over the cited Ying recipe. Accordingly, Applicant respectfully requests that the above rejection be reconsidered and withdrawn.

4. Claims 1-4 were rejected under §103(a) over Colarow or Ying in view of Kabushiki (Japanese article) and Kamarei. Applicant respectfully traverses this rejection. To the extent that this rejection might also be applied against new claims 5 and 6, it is respectfully traversed.

Independent claim 1 is discussed above in section 2. Claims 2-6 each depend from independent claim 1.

Since independent claim 1 defines patentable subject matter over the applied references for the reasons explained above, Applicant respectfully submits that dependent claims 2-6 likewise define patentable subject matter over the applied references by virtue of their dependency from claim 1. Accordingly, Applicant respectfully requests that the above rejection be reconsidered and withdrawn.

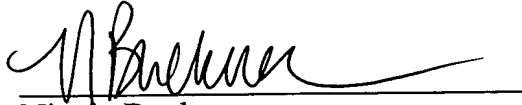
If the Examiner believes that contact with Applicants' attorney would be advantageous toward the disposition of this case, the Examiner is herein requested to call Applicants' attorney at the phone number noted below.

The Commissioner is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. 50-1446.

Respectfully submitted,

January 24, 2005

Date

  
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NB/gmh

Attachments: Appendix A - substitute specification  
Appendix B - marked-up specification  
Appendix C - replacement Abstract

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